DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

Mr. Jason Swift
Vice President of Operations
OBP Medical
360 Merrimack Street, Bldg. #9
Lawrence, MA 01843

Re: K091838
Trade/Device Name: OBP Self-Sealing Endoscopic Seal
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH, ODC, HET
Dated (Date on orig SE ltr): November 12, 2009
Received (Date on orig SE ltr): November 17, 2009

Dear Mr. Swift,

This letter corrects our substantially equivalent letter of December 4, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091838

Device Name: OBP Self-Sealing Endoscopic Seal

Indications For Use:

The OBP Self-Sealing Endoscopic Seal is a single use, sterile endoscopic introducer seal. It is affixed to the proximal port of the endoscope working channel. It prevents efflux of distention fluid when the channel is not being used or when instruments are passed through the working channel of the endoscope. The seal may be used with following types of endoscopes:

- hysteroscope
- laparoscope
- cystoscope
- colonoscope

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091838

510k Summary

DEC - 4 2009

510(k) Number (if known): K091838

Device Name: OBP Self-Sealing Endoscopic Seal

510k Summary:

Premarket Notification 510(k) Summary

Prepared By:	OBP Corporation
Telephone Number: Fax Number:	857-453-2492 866-636-2718
Contact Persons:	Dr. Keith Isaacson / Jason Swift
Trade Name:	OBP Self Sealing Endoscopic Seal with Luer Lock
Classification Name:	Hysteroscopic/Cystoscopic/Laparoscopic/Colonoscopic accessory
Common Name:	Seal with Luer Lock
Classification: Regulation Number:	Class II 21 CFR 876.1500 and 884.1690

Description of Device:

The OBP Self-Sealing Endoscopic Seal is a single use, sterile endoscopic introducer seal. It is affixed to the proximal port of the endoscope working channel. It prevents efflux of distention fluid when the channel is not being used or when instruments are passed through the working channel of the endoscope. The seal may be used with following types of endoscopes: hysteroscope, laparascope, cystoscope, and colonoscope. The seal comes with 4 different size channels to accommodate different size instruments. They are: 0.6mm, 1.2mm, 1.6mm, and 2.0mm. The 4 different seals are marked with different colored bands: yellow (0.6mm seal), light pink (1.2mm seal), green (1.6mm seal), and blue (2.0mm seal).